

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Richard M. O'Hara *et al.*

Attorney Docket No.: WYS-007.01

Serial No: 10/076,934

Confirmation No.: 3689

Filed: February 15, 2002

Art Unit: 1644

For: *Method for Downmodulating Immune
Response in Type I Diabetes*

Examiner: I. Ouspenski

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Sir:

In response to the Decision on the Request for Reconsideration of Patent Term Adjustment mailed on March 24, 2009 (attached as Appendix A), Applicants hereby request reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment ("PTA") determined in the aforementioned Decision. This Request for Reconsideration is based on the Office's failure to issue the patent within three years. As indicated in the attached Decision, there is no fee associated with this Request. However, if any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to **Deposit Account No. 06-1448, Reference No. WYS-007.01.**

The Notice of Allowance mailed July 16, 2008 indicated a PTA of 137 days. For the reasons given below, Applicants request correction of the PTA to 594 days.

This request for reconsideration is timely because it is filed within two months of the issue date of the patent.

A. Statement of Facts

1. Correct PTA and bases under § 1.702.

The correct PTA is 594 days. The patent is entitled to PTA under 37 C.F.R. §§ 1.702(a)(1) and 1.702(b).

2. Relevant dates as specified in §§ 1.703(a)-(e) and adjustment as specified under 1.703(f).

a. Application No. 10/076,934 was filed under 35 U.S.C. § 111(a) on February 15, 2002.¹

b. A Restriction Requirement was mailed on September 3, 2004, which was 507 days after the day that was 14 months after the filing date (i.e., April 15, 2003).

c. The application had been pending 3 years as of February 15, 2005.

d. Applicants filed a Request for Continued Examination under 35 U.S.C. § 132(b) on May 18, 2006.

e. The pendency time after the 3-year period not consumed by continued examination was 457 days, i.e., from February 15, 2005 to May 18, 2006.

f. The total delay under 37 C.F.R. § 1.702(a)(1) was 507 days, the time period from April 15, 2003 to the mailing of the Restriction Requirement on September 3, 2004.

g. The total delay under 37 C.F.R. § 1.702(b) was 457 days, the time period from the beginning of three years' pendency on February 15, 2005 to the filing of a request for continued examination on May 18, 2006.

h. The delays specified in paragraphs (f) and (g) total 964 days.

i. The adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled is 964 days, less the sum of periods calculated under 37 C.F.R. § 1.704, addressed below.

3. The patent is not subject to a terminal disclaimer.

4. Circumstances constituting failure to engage in reasonable efforts.

a. Applicants' response to the Notice to File Missing Parts was filed 1 day after the date that was three months after the Notice was mailed.

b. Applicants' reply under 37 C.F.R. § 1.111 of June 27, 2005 was filed 92 days after the date that was 3 months after the prior action was mailed.

c. Applicant's first Notice of Appeal of March 15, 2006 was filed 91 days after the date that was 3 months after the final action of September 14, 2005 was mailed.

¹ The application was originally accorded a filing date of 2/19/2002, which was corrected to 2/15/2002 on petition.

d. Applicants' reply under 37 C.F.R. § 1.111 of January 25, 2007 was filed 92 days after the date that was 3 months after the prior action was mailed.

e. Applicant's second Notice of Appeal of September 10, 2007 was filed 94 days after the day that the final action of March 8, 2007 was mailed.

f. Applicant's total delay under 37 C.F.R. § 1.704 was 370 days. The adjustment as specified in 1.703(f) to which the patent is entitled is reduced, therefore, by 370 days.

g. The adjustment as specified in 1.703(f) to which the patent is entitled is 964 - 370 = 594 days.

B. Argument

Applicants request correction of the PTA because the Office delay of 457 days for pendency beyond 3 years (not including time consumed by continued examination) does not overlap any other delay, pursuant to the holding in *Wyeth v. Dudas*, No. 07-1492 (D.D.C. Sept. 30, 2008) ("Memorandum Opinion" and Order) (copy attached to this request as Exhibit A).

In its "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)" published on June 21, 2004, at 69 Fed. Reg. 34238, the Office took the position that "the entire period during which the application was pending before the Office . . . , and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay 'overlap' under 35 U.S.C. § 154(b)(2)(A)." Under this interpretation, the Office delay discussed above in paragraph 2(b) would be considered to "overlap" under 25 U.S.C. § 154(b)(2)(A).

But in a Memorandum Opinion and Order issued on Sep. 30, 2008 in *Wyeth v. Dudas*, Civil Action No. 07-1492, the U.S. District Court for the District of Columbia held that the Office's "Explanation" and "Interpretation" of 35 U.S.C. § 154(b)(2)(A) is invalid because it is inconsistent with the plain text of the statute. The Court held that periods of delay that do not occur on the same calendar days as one another cannot be considered to "overlap," for the simple reason that they do not occur on the same days. The Court dismissed the Office's argument that the 3-year delay begins with the filing of application and instead held that the 3-year delay begins only when the Office has failed to issue a

patent within 3 years of filing, not before. Thus, any delays attributable to the office that occur before the application was pending for 3 years cannot, as a matter of law, be considered overlapping with the delay period that commences at 3 years' pendency.

Under the Court's holding, which is binding on the Office, the Office delay discussed above in paragraph 2(b) (concerning the delay to issuance of the Restriction Requirement) occurred before the 3-year delay period started and so does not overlap with it.

For these reasons, Applicants' patent is entitled to 457 days' adjustment under 37 C.F.R. § 1.702(b) as non-overlapping with the 507 days' adjustment under 37 C.F.R. §§ 1.702(a)(1), for a total adjustment of 964 days less 370 days' delay attributable to Applications, giving a PTA of 594 days under 37 C.F.R. § 1.703(f). Applicants request the issuance of a certificate of correction showing that the PTA is corrected from 137 days to 594 days.

Respectfully submitted,

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Dated: July 8, 2009
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| In re Application of | : | |
| O'Hara, et al. | : | PATENT TERM ADJUSTMENT |
| Application No. 10/076,934 | : | |
| Filed: February 15, 2002 | : | |
| Atty Docket No. WYS-00701 | : | |

This decision is in response to the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT," filed October 16, 2008. Applicants request that the initial determination of patent term adjustment under 35 U.S.C. 154(b) be corrected from 137 days to 594 days.

The Determination of Patent Term Adjustment under 35 U.S.C. 154(b) was mailed July 16, 2008. The instant application for patent term adjustment and issue fee payment were timely filed October 16, 2008. Prior to a decision on the application for patent term adjustment being rendered, on December 3, 2008, applicants filed a petition to withdraw from issue along with a request for continued examination (RCE). The application was withdrawn from issue December 4, 2008.

Nevertheless, applicants request correction of the adjustment on the basis that the Office will take in excess of three years to issue this patent and also in light of the recent court decision in *Wyeth v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008).

A decision in this regard is being **held in abeyance** until after the actual patent date. Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term for Office failure to issue the patent within three years. See, 37 CFR 1.703(b).

Applicants are given **TWO (2) MONTHS** from the issue date of the patent to file a written request for reconsideration of the patent term adjustment for Office failure to issue the patent within three years. A copy of this decision should accompany the request. Applicants may seek such consideration without payment

of an additional fee. However, as to all other bases for seeking reconsideration of the patent term adjustment indicated in the patent, all requirements of 37 CFR 1.705(d) must be met. Requests for reconsideration on other bases must be timely filed and must include payment of the required fee.

Technology Center AU 1644 has been advised of this decision. The application is, thereby, forwarded to the Technology Center 1644 for consideration of the RCE by the examiner.

Telephone inquiries specific to this decision should be directed to Alesia M. Brown, Petitions Attorney, at (571) 272-3205.

Kery Fries

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Senior Legal Advisor
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Office of Deputy Commissioner
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